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| PPLICATION NO.                            | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|---|-----------------|----------------------|-------------------------|-----------------|
| 09/805,020                                | 03/13/2001      | Zurit Levine         | 2786-0168P              | 9282            |
| 2292 75                                   | 590 1 1/09/2004 |                      | EXAMINER                |                 |
| BIRCH STEWART KOLASCH & BIRCH             |                 |                      | HUFF, SHEELA JITENDRA   |                 |
| PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |                 |                      | ART UNIT                | PAPER NUMBER    |
|   |                 |                      | 1642                    |                 |
|   |                 |                      | DATE MAILED: 11/09/2004 |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.          | Applicant(s)                |  |  |  |  |
|---|--------------------------|-----------------------------|--|--|--|--|
|   |                          |                             |  |  |  |  |
| Office Author Commence  | 09/805,020               | LEVINE ET AL.               |  |  |  |  |
| Office Action Summary   | Examiner                 | Art Unit                    |  |  |  |  |
|   | Sheela J Huff            | 1642                        |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                          |                             |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                          |                             |  |  |  |  |
| Status  |                          |                             |  |  |  |  |
| 1) Responsive to communication(s) filed on 27 September 2004 and 13 October 2004.   |                          |                             |  |  |  |  |
| 2a)⊠ This action is <b>FINAL</b> . 2b)□ This action is non-final.   |                          |                             |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |                          |                             |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |                          |                             |  |  |  |  |
| Disposition of Claims   |                          |                             |  |  |  |  |
| 4)⊠ Claim(s) <u>3,41 and 42</u> is/are pending in the application.  |                          |                             |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                          |                             |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                          |                             |  |  |  |  |
| 6) Claim(s) 3,41 and 42 is/are rejected.  |                          |                             |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                          |                             |  |  |  |  |
| 8) Claim(s)are subject to restriction and/or election requirement.  |                          |                             |  |  |  |  |
| Application Papers  |                          |                             |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |                          |                             |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |                          |                             |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                          |                             |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |                          |                             |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |                          |                             |  |  |  |  |
| Priority under 35 U.S.C. § 119  |                          |                             |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                          |                             |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |                          |                             |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                          |                             |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                          |                             |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |                          |                             |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |                          |                             |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |                          |                             |  |  |  |  |
|   |                          |                             |  |  |  |  |
| Attachment(s)   |                          |                             |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |                          |                             |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Da      | ite                         |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 5)  Notice of Informal P | atent Application (PTO-152) |  |  |  |  |

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#### **DETAILED ACTION**

### Response to Amendment

The amendment filed on 9/27/04 and the declaration filed 10/13/04 have been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 3 and 41-42 are pending.

The rejection of the claims under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment.

The rejection of claims 3-4, 13(in-part)-15 and 17-18 under 35 U.S.C. 112, first paragraph, (pages 7-8 of the paper mailed 4/14/04) is withdrawn in view of applicant's amendment.

The rejection of claims 13(in-part)-15 and 17-18 under 35 U.S.C. 112, first paragraph, (pages 9-11 of the paper mailed 4/14/04) is withdrawn in view of applicant's amendment.

## Response to Arguments

## Claim Rejections - 35 USC § 101/112

Claims 3 and 41-42 remain/are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility. The reasons for this rejection are of record in the paper mailed 4/14/04.

Applicant argues that PKC is well known in the art and the domains are well characterized. The Examiner is not disputing this. Applicant's invention is drawn to a

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variant of PKC which has a different protein kinase domain and as stated in applicant's response (page 7 bottom) "it is expected that protein kinase activity is affected but not abolished" (emphasis added). Thus, without objective evidence to show that applicant's variant has activity, even applicant is unsure the level of activity of the variant.

Claims 3, 41-42 remain/are also rejected under 35 U.S.C. 112, first paragraph. The reasons for this rejection are of record in the paper mailed 4/14/04.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-

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0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff Primary Examiner Art Unit 1642

sjh